Remarks

The following is a response to the Office Action dated January 13, 2003 in which claims 1-2 and 8-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Brain et al. (WO 00/61213) and claim 4 was rejected under 35 U.S.C. 103(a) as being obvious over the combination of Brain and Sato (US 5392774).

Per the above amendment, claim 1 has been amended to recite that the tube and mount are injection moulded together as an integral, single piece unit.

This distinguishes from the Brain citation where the tube and mount are made by rotational moulding.

In the rotational moulding process, a quantity of a liquid plastic is introduced into a hollow mould and the mould is rotated so that the plastic coats its interior surface. The mould defines the exterior surface of the product being moulded but not its interior surface. Whilst it might be possible to introduce some variation in wall thickness over the product by arranging for the plastic to slop more over the parts that are to be thicker, it is very difficult to produce accurate control of wall thickness. Another problem with rotational moulding is that only certain plastics can be used, which may not be ideal for every application.

In the present invention, the mount and tube are made by an injection moulding process. Such processes involve a cavity that is filled with the plastic material so that both external and internal surfaces of the finished product are defined by the surfaces of the cavity. In this way, very accurate control of wall thickness can be achieved and thickness can be varied over different regions. In the laryngeal mask made by the present invention this high degree of control achieved by selection of the injection moulding process enables the flexibility of the tube and mount to be controlled so that the flexibility can differ at different locations along the length of the device in the manner best suited to the clinical uses of the mask.

It is not at all obvious that injection moulding would be a suitable process for forming a laryngeal mask for the reasons set out in paragraph 11 of the Declaration of Michael Collins but, surprisingly, it has enabled a high quality laryngeal mask to be achieved as can be seen by the sample provided with the Declaration.

New claims 11-15 have been added per the above amendment. The subject matter of the newly added claims is supported by the first 2 sentences in the last paragraph on page 3 of the disclosure and the drawing.

As it can be seen, the cuff in the device of the instant invention encircles the edge of the patient end of the mount. In contrast, the Brain reference requires that there be a plate 440 (Fig 5A) to which the cuff is attached. As further shown by Figs 5B-5C and 9A-9G and other figures, as well as the disclosure (page 14, lines 11-18; page 15, lines 8-15; p 21, lines 4-7 and 26-29), the edge of the plate for the mount of the Brain device is exposed. According to the disclosure from page 35, line 6 to page 36, line 9 and Figs 15A-15B, the configuration of the Brain mask is important. Thus, the way in which the cuff is attached to the mount in the claimed device is different from, and indeed the Brain reference teaches away from, because the mask of the instant invention is able to protect the tissues of the patient whereas the exposed edge of the mount of the Brain device may not.

In view of the foregoing, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,

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